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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,508	08/15/2002	Sai L. Su	020093-001000US	5007

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,508	SU, SAI L.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-29 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 7, 8, and 11, insofar as the claims are drawn to a method for detecting a prostate cell having metastatic potential, said method comprising detecting the expression of flt-4 in a prostate cell using an antibody or a portion thereof that binds flt-4.

Group II, claim(s) 1-4, 6-8, and 11, insofar as the claims are drawn to a method for detecting a prostate cell having metastatic potential, said method comprising detecting the expression of flt-4 in a prostate cell using a nucleic acid molecule comprising a nucleotide sequence consisting of at least 6 contiguous nucleotides of the complement of SEQ ID NO: 1.

Group III, claim(s) 12, drawn to a method for determining the prognosis of a subject with prostate cancer, said method comprising identifying a prostate cancer cell in a body fluid sample obtained from the subject and detecting the expression of flt-4 in the cell.

Group IV, claim(s) 13, 14, and 15, insofar as the claims are drawn to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, said

method comprising administering to a subject a protein comprising a fragment of flt-4 consisting of at least the amino acid sequence of SEQ ID NO: 2.

Group V, claim(s) 13 and 16, insofar as the claims are drawn to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, said method comprising administering to a subject a nucleic acid molecule comprising a nucleotide sequence encoding a fragment of flt-4.

Group VI, claim(s) 13, 17, and 18, insofar as the claims are drawn to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, said method comprising administering to a subject an antisense oligonucleotide comprising a nucleotide sequence consisting of at least 6 contiguous nucleotides of the complement of SEQ ID NO: 1.

Group VII, claim(s) 13 and 19, insofar as the claims are drawn to a method for treating, inhibiting or preventing a secondary prostate tumor metastasis, said method comprising administering to a subject a an antibody or a portion thereof that binds flt-4.

Group VIII, claim(s) 20, drawn to a method for screening for a molecule that treats, inhibits or prevents a secondary prostate tumor metastasis, said method comprising contacting a prostate cancer cell with a candidate molecule and comparing the level of expression of flt-4 in the cell with the level of expression in a cell no so contacted.

Group IX, claim(s) 21 and 22, drawn to a method for screening for a molecule that treats, inhibits or prevents a secondary prostate tumor metastasis, said method comprising measuring the levels of complex formed from flt-4 and VEGF-C in the presence and absence of a candidate molecule.

Group X, claim(s) 23, drawn to a method for monitoring the efficacy of treatment or inhibition of metastatic prostate cancer, said method comprising measuring the level of expression or activity of flt-4 in prostate cells obtained from a subject.

Group XI, claim(s) 24 and 25, drawn to a composition comprising a protein comprising a fragment of flt-4 consisting of at least the amino acid sequence of SEQ ID NO: 2.

Group XII, claim(s) 26, drawn to a composition comprising a nucleic acid molecule comprising a nucleotide sequence encoding a fragment of flt-4.

Group XIIII, claim(s) 27 and 28, drawn to a composition comprising an antisense oligonucleotide comprising a nucleotide sequence consisting of at least 6 contiguous nucleotides of the complement of SEQ ID NO: 1.

Group XIV, claim(s) 29, drawn to a composition comprising an antibody or a portion thereof that binds flt-4.

3. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is detecting a prostate cell having metastatic potential by a process comprising detecting the expression of flt-4 in a prostate cell using an antibody or a portion thereof that binds flt-4.

The special technical feature of Group II is detecting a prostate cell having metastatic potential by a process comprising detecting the expression of flt-4 in a prostate cell using a nucleic acid molecule comprising a nucleotide sequence

consisting of at least 6 contiguous nucleotides of the complement of SEQ ID NO: 1.

The special technical feature of Group III is determining the prognosis of a subject with prostate cancer by a process comprising identifying a prostate cancer cell in a body fluid sample obtained from the subject and detecting the expression of flt-4 in the cell.

The special technical feature of Group IV is treating, inhibiting or preventing a secondary prostate tumor metastasis by a process comprising administering to a subject a protein comprising a fragment of flt-4 consisting of at least the amino acid sequence of SEQ ID NO: 2.

The special technical feature of Group V is treating, inhibiting or preventing a secondary prostate tumor metastasis by a process comprising administering to a subject a nucleic acid molecule comprising a nucleotide sequence encoding a fragment of flt-4.

The special technical feature of Group VI is treating, inhibiting or preventing a secondary prostate tumor metastasis by a process comprising administering to a subject an antisense oligonucleotide comprising a nucleotide sequence consisting of at least 6 contiguous nucleotides of the complement of SEQ ID NO: 1.

The special technical feature of Group VII is treating, inhibiting or preventing a secondary prostate tumor metastasis by a process comprising administering to a subject a an antibody or a portion thereof that binds flt-4.

The special technical feature of Group VIII is screening for a molecule that treats, inhibits or prevents a secondary prostate tumor metastasis by a process

comprising contacting a prostate cancer cell with a candidate molecule and comparing the level of expression of flt-4 in the cell with the level of expression in a cell no so contacted.

The special technical feature of Group IX is screening for a molecule that treats, inhibits or prevents a secondary prostate tumor metastasis by measuring the levels of complex formed from flt-4 and VEGF-C in the presence and absence of a candidate molecule.

The special technical feature of Group X is monitoring the efficacy of treatment or inhibition of metastatic prostate cancer by measuring the level of expression or activity of flt-4 in prostate cells obtained from a subject.

The special technical feature of Group XI, is making a composition comprising a protein comprising a fragment of flt-4 consisting of at least the amino acid sequence of SEQ ID NO: 2.

The special technical feature of Group XII is making a composition comprising a nucleic acid molecule comprising a nucleotide sequence encoding a fragment of flt-4.

The special technical feature of Group XIIII is making a composition comprising an antisense oligonucleotide comprising a nucleotide sequence consisting of at least 6 contiguous nucleotides of the complement of SEQ ID NO: 1.

The special technical feature of Group XIV is making a composition comprising an antibody or a portion thereof that binds flt-4.

Although the inventions of Groups I and II appear to be linked by the same or a corresponding technical feature, since each is a method for detecting a prostate cell

having metastatic potential, said method comprising detecting the expression of flt-4 in a prostate cell, Tsurusaki et al. (Br. J. Cancer. 1999 Apr; 80 (1/2): 309-313) teaches VEGF-C expression in prostatic carcinoma and its relationship to lymph node metastasis, which suggests that detecting the expression of flt-4/VEGFR-3, the receptor of VEGF-C, provides an indication of the presence of prostate cancer cells having the potential to metastasize. Therefore, this technical feature that appears to link the inventive concepts of Groups I and II does not constitute a special technical feature as defined by PCT Rule 13.1, as it does not define a contribution over the prior art.

With regard to the inventions of Groups IV-VII, the alternative embodiments of claim 13 are not "alternatives of a similar nature"; nor do they share the same or corresponding technical feature that defines a significant contribution over the prior art with regard to their novelty or inventive step. Alternatives of a claimed invention should have a common property or activity and a common, substantial structural feature, which correlates with the presence of the common property or activity, or in the absence of such common, substantial structural feature, belong to a recognized class of chemical compounds, where there is an expectation from the knowledge in the art that at least most members of the class will behave in the same way in the context of the claimed invention. Claim 13 is drawn to a method for treating, inhibiting or preventing a secondary prostate cancer metastasis comprising administering to a subject in need of such a molecule that inhibits the activity or expression of flt-4; however, the specifically claimed alternatives comprises administering to the subject a molecule that does not appear to share a similar structure or function; moreover, despite sharing an ability to inhibit either the activity or expression of flt-4, the different molecules have different modes of operation.

In addition, PCT Rules 13.1 and 13.2 do not provide for unity of invention comprising more than the first mentioned product, the first mentioned method for using said product, and the first mentioned method for making said product.

Accordingly, the inventions of Groups I-XIV do not share the same or corresponding special technical feature, so as to form a single general inventive concept under PCT Rules 13.1. and 13.2.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
July 13, 2005